User Manual

C-Trak® Analyzer

Automatic Analyzer and Probe System

CARE WISE

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Warranty

Care Wise warrants new analyzers, probes, and related products addressed in this Product Manual to be free of defects due to workmanship, materials and design for a period of twenty-four (24) months from date of delivery. Refurbished products are warranted for twelve (12) months and product repairs are warranted for ninety days. Damage resulting from misuse by the owner or its agent(s) will be the sole responsibility of the owner.

In event of instrument failure, the owner must notify Care Wise for repair or replacement. Liability of this warranty is limited to the purchase price of the instrument. Electrical safety must be periodically checked at the hospital in which this device is used in accordance with The Joint Council (TJC) standards and procedures.

User servicing or disassembly of any portion of this system voids the warranty. The individual performing unauthorized disassembly and the owner of the system assumes sole liability for damage to the system and any consequential damages.

Receiving Condition Examination

Owner is responsible for inspecting the shipping carton for visible damage when it is delivered by the carrier. If damage to the shipping carton is visible the carrier should be notified immediately that the carton was received in damaged condition.

Should the instrument be received in a damaged condition, save the shipping container and the packing material and request an immediate inspection by the carrier.

Care Wise is not responsible for any damage that occurs during shipment. Please contact our office if we can be of assistance in resolving the damage claim with the carrier.

Return of Goods to Manufacturer

All equipment being returned for repair or evaluation, whether under warranty or not, must receive return authorization from Care Wise prior to shipment and be assigned an RMA number. The C-Trak® instrument must be returned in the original shipping container (box) or in a container that will adequately protect the product. Do NOT ship in just the carrying case! All shipments should include documentation containing customer name, shipping address, telephone number and any other necessary information. Please call if there are any questions regarding the packing material and cartons.

Ship to:

Europe & Worldwide:

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Tel: US (813) 626-6848
Fax: US (813) 620-3708
Web: www.carewise.com

Your cooperation will expedite the return of your equipment.

Equipment being returned, for any reason, MUST be clean and disinfected. A signed and completed copy of the Care Wise Proof of Cleaning Statement (Appendix G) must accompany any returned product. Items returned without this form, as well as any contaminated items, will be returned at the expense of the party returning the equipment. Once evaluated, the customer must issue a hard copy purchase order for the total repair cost prior to commencement of the repairs. No product will be returned without a purchase order.

1.0 Introduction

1.0 C-Trak® Analyzer and Probe

The C-Trak® system has been designed to detect and quantify the nuclear radiation from gamma emitting isotopes. The system is comprised of a probe and an automatic analyzer.

The probe (or "detector") is capable of detecting gamma ray energies up to 364 keV. The analyzer is designed for operation with scintillation detectors (probes).

C-Trak® probes have special collimation and shielding that allow highly directional detection of radiation from sites of interest along with greatly reduced detection of background radiation.

The battery-powered analyzer is designed to operate the probe, display the data from the detected radiation, and display and control the system's operating parameters. The result is optimum performance in measuring gamma radiation from isotopes such as Technetium- 99m and Indium-111.

Comprehensive shielding of high voltage sites within the instrument and operation only from internal batteries eliminate the possibility of significant electrical current leakage to patient or user under normal operating conditions. The C-Trak® system's electrical safety is greatly enhanced by the fact that the system is not designed or manufactured to be connected to an AC power line or any other type of external power supply. The system has been designed and manufactured for safe operation in an operating room environment, as long as flammable anesthetic gasses are not used.

1.1 Product Manual

Sections 2.0 ("Getting Acquainted...") and 3.0 ("Calibration Checking") provide information to help you become familiar and comfortable with the system and the various screens and calibration check steps.

Section 4.0 presents the calibration procedure. Section 5.0 outlines the pre-surgery set up requirements and Section 6.0 the steps for actual use during surgery.

Sections 7.0, 8.0, 9.0, 11.0 and 12.0 provide important cleaning, safety and technical information.

Section 10.0 addresses the various accessories available for the C-Trak® system and how to use them.

If you don't find the answer there, contact your responsible department or call Care Wise on +1-813-626-6848 (USA & Canada) +44 1273 497600 (Europe & Worldwide)

2.0 Getting acquainted with the C-Trak® System

2.1 Front Panel

(1) Main Power – Turns the main battery power supply on and off. A green LED is lighted when main power is on.

(2) Reserve Power – Turns the reserve battery power supply on and off. A green LED is lighted when reserve power is on.

(3) Display Screens – Depending on the specific screen selected, displays the data on radiation detected by the system, the specific configuration of the system when in use, or the information needed to reconfigure the system when desired.

(4) Ratemeter Multiplier Selection Button – Allows selection of the multiplier (i.e., x1, x10, x100, x1000) for the ratemeter range. If "x10" is selected, the ratemeter range is from zero to 300 (30 x 10). An orange LED identifies the selected multiplier.

(5) Selection Buttons – Located above LCD display, they are used to select certain parameters and initiate certain processes, depending on the screen selected.

(6) Volume Control – Adjusts volume level of the audible tones that indicate the detected level of radioactivity (bar graph on LCD display indicates approximate volume level).

(7) Probe Connector – MHV style connector for all probes.

(8) Overload Indicator – If the current at the probe connector is more than 10 µ amps, the red indicator light is lighted and the power to the connector and the probe (if connected) is turned off.

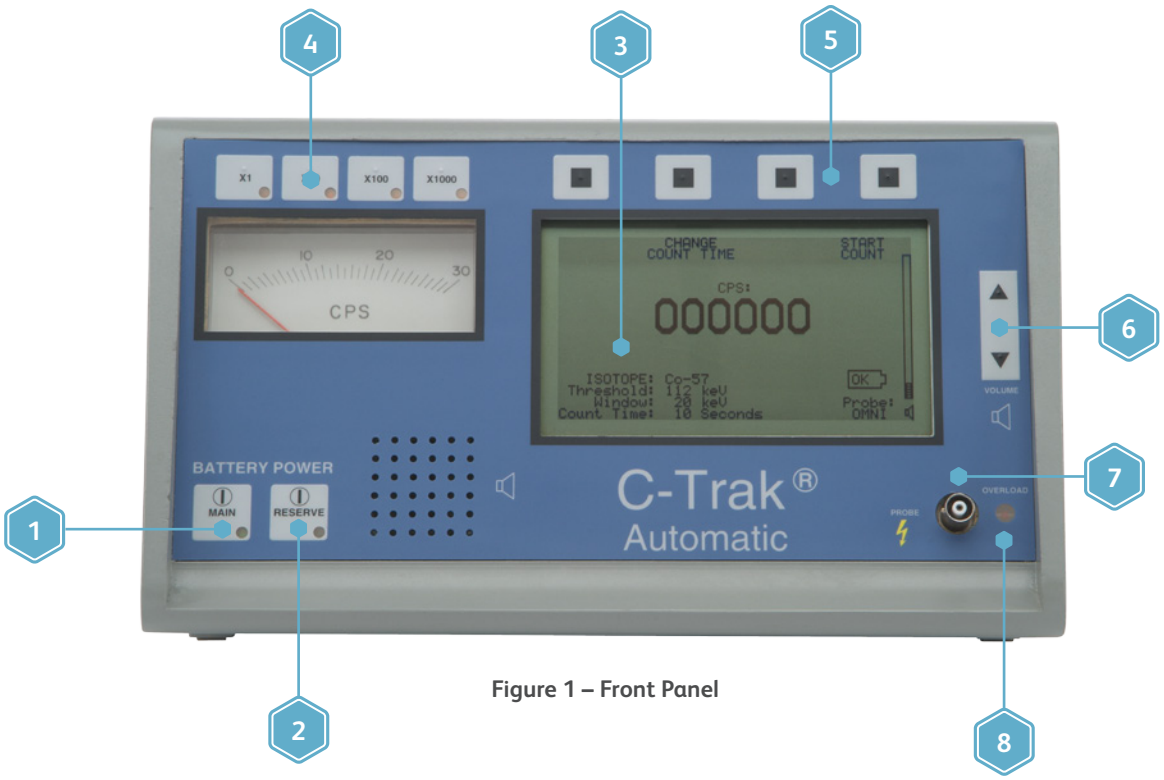


Figure 1 – Front Panel

2.2 Rear Panel

(1) BATTERY ACCESS PANEL – Provides access to the main and reserve batteries.

Tools are not required to remove and replace the batteries.

(2) PHA OUT – A BNC coaxial connector – designed primarily for connection to an external pulse height analyzer (PHA) or multi-channel analyzer.

(3) RS-232/PRINTER OUTPUT – Optically isolated serial data utilizing a 9-pin "sub-d" connector designed to operate external battery powered (no AC line connections permitted) printer; internal battery pack in the printer capable of operating the receiver part of the optical isolation system.

(4) LED REPEATER – LED display of timed counts, or counts-per-second, by a small unit that can be positioned as preferred by the user; e.g. hanging from an IV pole for a higher view or anywhere within the line of vision.

(5) FOOTSWITCH – External footswitch utilized to start the preset counting period.

Uses a 3-pin female Switchcraft SL173F connector.

(6) PROBE HOLDER/SOURCE DRAWER – On earlier models only.

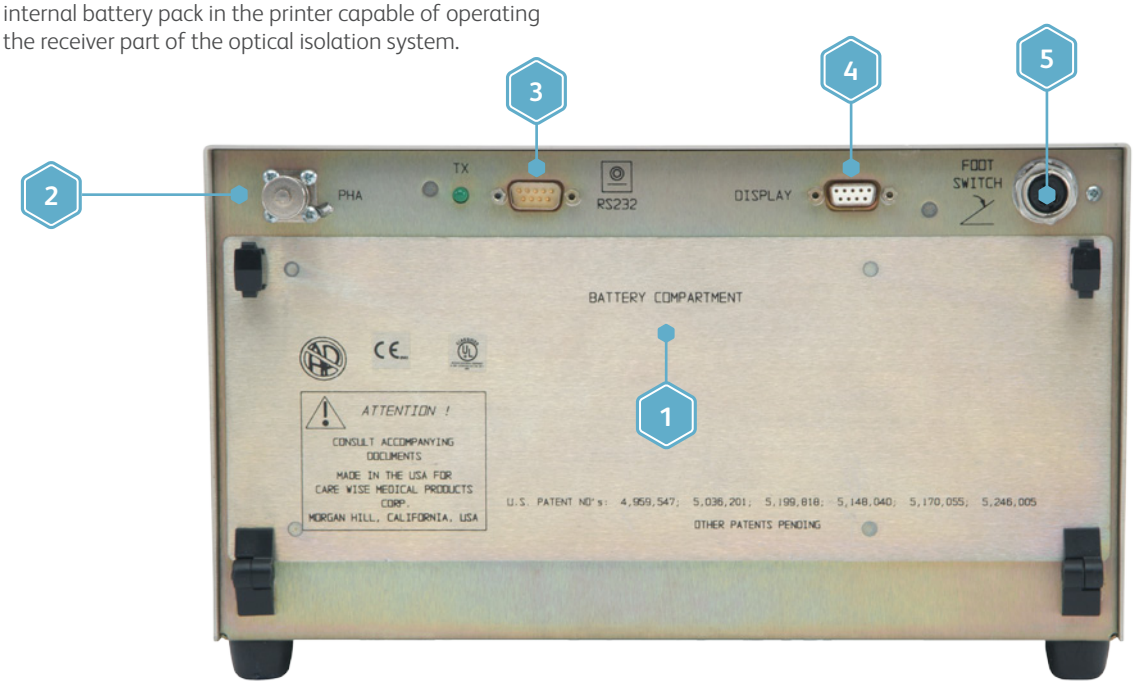


Figure 2 – Rear Panel

2.3 Side Panel

CONTROL WHEEL – A dial on the right side of the analyzer that allows user to access CONTROL SCREENS for advanced functions.

The control wheel is also used to edit settings on certain CONTROL and FACTORY SCREENS.

- Rotating the Control Wheel clockwise increases the number being edited.
- Rotating the Control Wheel counter-clockwise decreases the number being edited.

Figure 3 – Side Panel

2.4 Accessing the Screens

The following steps will guide you through the various screen options. It will take a minimum of 10 minutes to go through all the screens and then reset the analyzer. Take enough time to become familiar and comfortable with all the controls.

2.4.1

If you are just going to go through the screens, get the analyzer and turn it on. It is not necessary to have the probe connected or to have a check source.

2.4.2

If you want to go through the calibration check (and/or calibration) process you will need the analyzer, probe and a check source. Connect probe to analyzer then turn on analyzer. Insert probe and source in source holder.

2.4.3

The first screen to appear will be "WARM UP" (the PROBE...not the analyzer... needs to be "warmed up"). You can follow directions on screen and calibrate (see Section 4.0). OR – you can use the control wheel on the side to go directly to "Control Screen" and change to the various screens by following the screen options.

2.4.4

Continue going through the screens. Follow directions on how to select and save isotopes, edit isotopes, change count time, etc.

2.4.5

If the system is a newly purchased one from a "Third Party" and not calibrated, or if you are not sure about the calibration status: you should first follow the directions to "RESTORE FACTORY SETTINGS." Then proceed to SET UP and calibrate the system for the probe and clinical isotope you are using.

NOTE: As received from Care Wise Medical Products, the system will be calibrated and will have a completed "Bias Voltage Record" form included.

General Tips:

- To change screens, select fields, save or enter data or to exit; etc, press your choice on the button above the corresponding screen option.
- To change settings (numbers) on the screen, turn the Control Wheel while viewing screen.

Note: There may be differences in the screen on your analyzer from those presented here due to revisions to the system firmware over time.

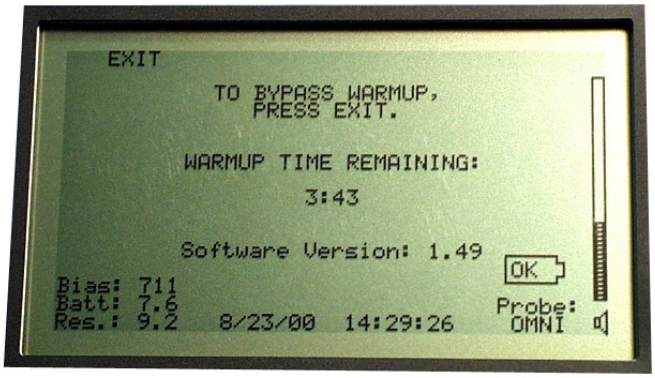


Figure 4 – Warm Up Screen

This screen appears while the system (the probe) is warming up. The countdown in the center of the screen will indicate when the system is ready for use.

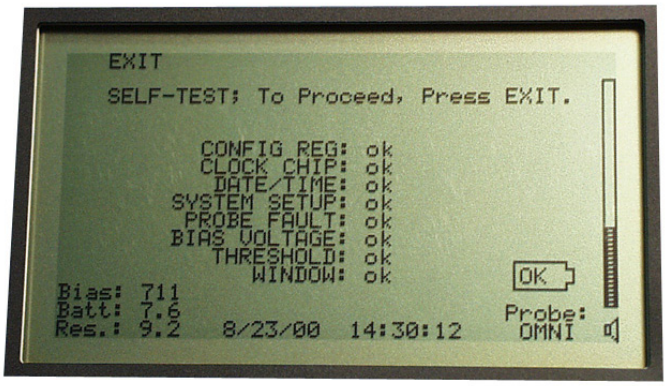


Figure 5 – Internal Diagnostic

If a problem occurs in the system while doing calibration check or if the red overload indicator light goes on, the screen you are using will be replaced by the Internal Diagnostic screen. If one or more items are not "ok" but instead read "Failed," see Appendix C for corrective action.

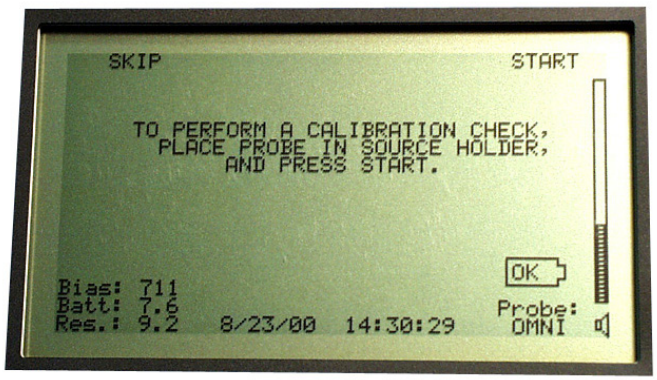


Figure 6 – Calibration Check

This screen shows the system is ready for a calibration check.

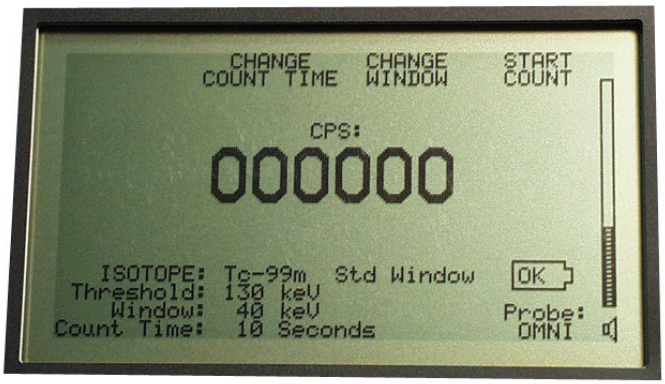


Figure 7 – Home Screen

This is the primary screen seen in clinical use. Radiation counts are displayed, along with parameters selected and cps or timed count data.

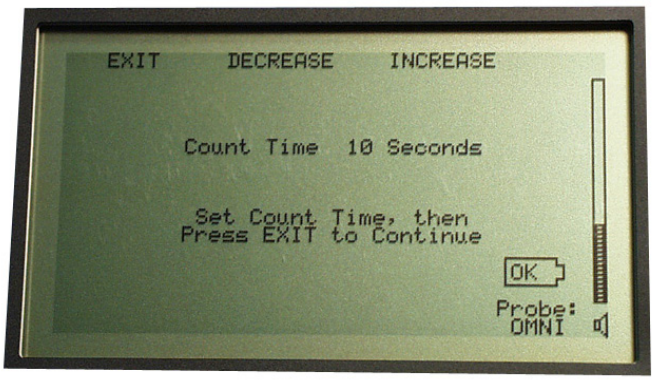


Figure 8 – Count time Screen

This screen allows you to specify the duration of timed counts. The default time is 10 seconds.

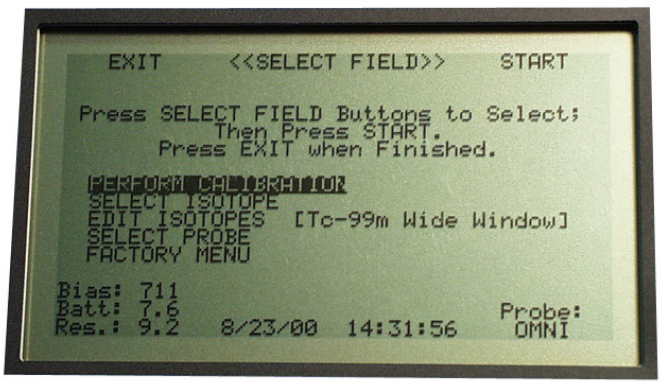


Figure 9 – Master Control

Turning the control wheel on the side of the analyzer allows access to the Master Control Screen.

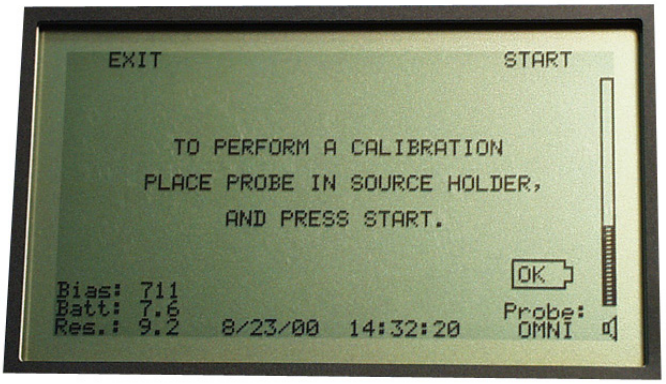


Figure 10 – Perfrom Calibration

Can be manually accessed via the Master Control screen in order to recalibrate the analyzer with a probe. Note, however, that if calibration checks are performed regularly, the system is already confirmed to be in calibration.

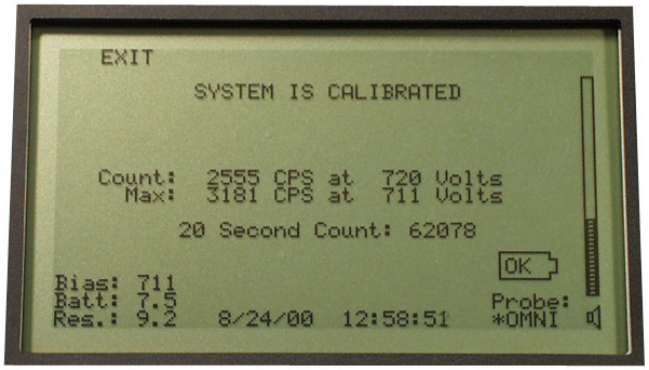


Figure 11 – Calibration

Displayed at conclusion of calibration process.

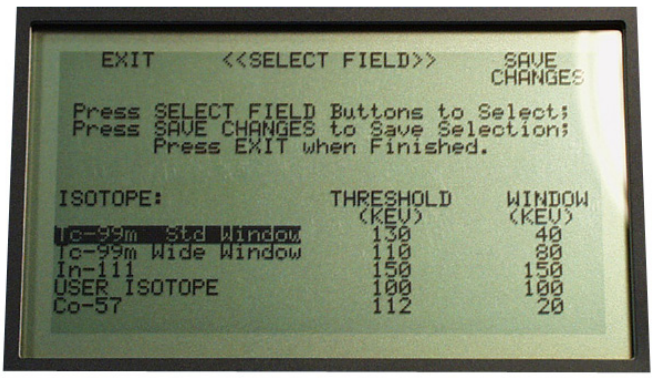


Figure 12 – Select Isotope

Allows you to select an isotope for clinical use. If neither Tc-99M or In-111 is being used, select USER ISOTOPE and customize setting as necessary in EDIT ISOTOPE screen.

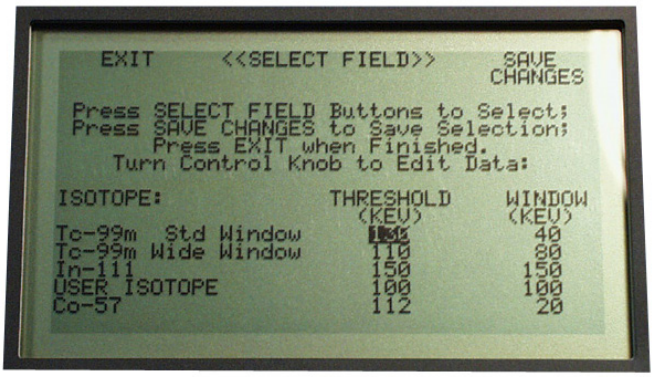


Figure 13 – Edit Isotope

Allows you to change the values preset by the factory. User custom values for an isotope not shown may also be entered.

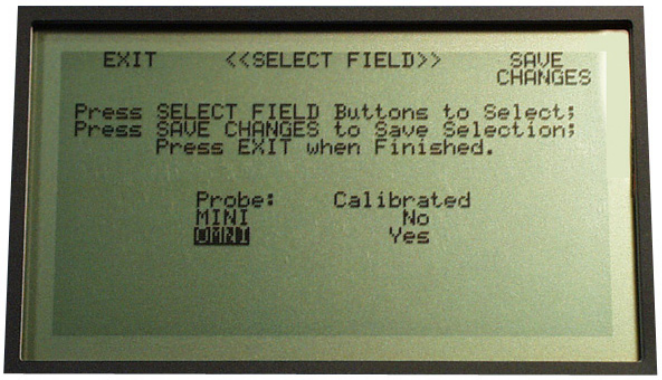


Figure 14 – Select Probe

Allows you to switch from one C-Trak® probe to another. Calibration settings for two different probes are retained by the system; designated Mini and Omni on the screen, You may have two OmniProbes by using the Mini values for your second Omni. Be sure probe you are using is displayed.

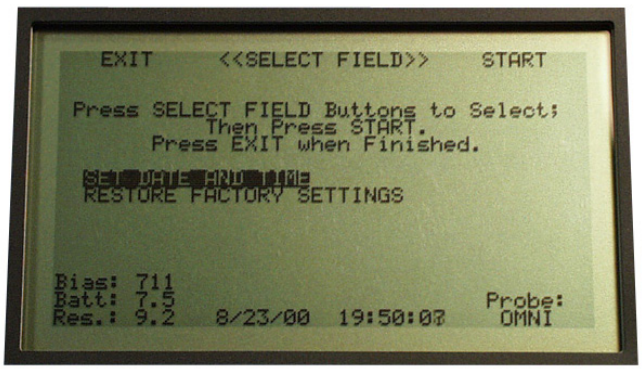


Figure 15 – Factory Menu

Allows you to set date and time and restore Factory Settings.

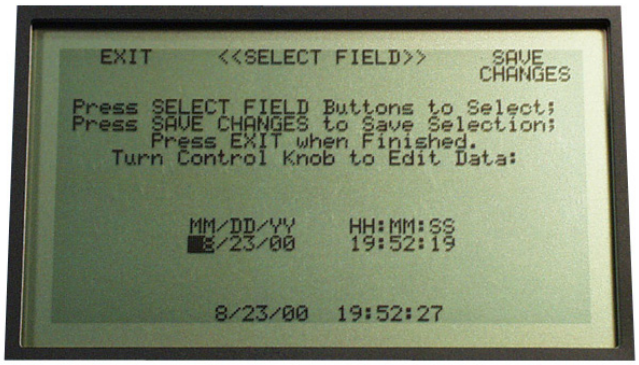


Figure 16 – Set Date and Time

Allows you to set the internal system clock.

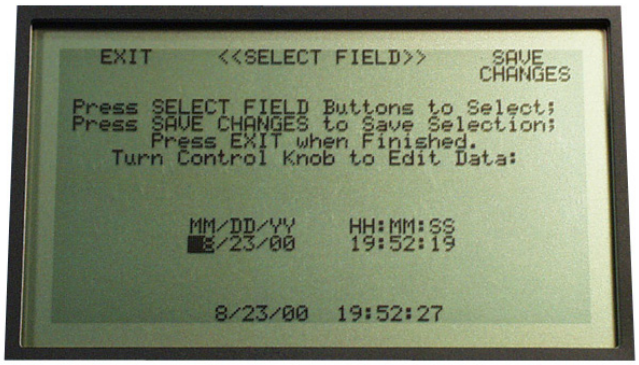


Figure 17 – Restore Factory Settings

Restores all system settings to factory default values. Deletes calibration data, all user-defined isotope settings and returns Bias Voltage to 700 V default value.

NOTE: System must be recalibrated after restoring factory settings.

3.0 Calibration Checking

3.1 When To Do Calibration Check

Your C-Trak® system needs to be calibrated to ensure optimal sensitivity. Also, if you are using a different probe or check source, you will need to calibrate.

- Calibration check need only be done once a week and that would be prior to the first surgery of the week. Routine calibration checks should be performed weekly to ensure optimal performance of your C-Trak® system. If you use the system less than once a week, check the calibration before using.

The calibration check is fully automated and once the system (i.e. the probe) is warmed up, takes approximately 30 seconds.

3.2 Isotope Source

A Cobalt 57 (Co-57) check source can be used to set up a system intended for use with either Indium 111 (In-111) or Technetium 99m (Tc-99m). The characteristics of Cobalt 57 are:

Primary photo peak energy: 122 keV

Half life (time it takes for activity to decay by one-half) 271 days.

- A Co-57 source comes as part of the C-Trak® system. The five µCi co-57 check source should be replaced at least every 18 months. For information on obtaining a check source, contact Care Wise.

3.3 Performing Calibration Check

- DO NOT BYPASS WARM UP OF PROBE WHEN DOING CALIBRATION CHECK.
- Connect probe and turn on analyzer.

After turning on the analyzer, a screen will be displayed that counts down from 5 minutes. The probe will be warmed up when the clock reaches zero. This ensures that your C-Trak® probe will have maximum sensitivity during the calibration check procedure and during any clinical procedures.

The next screen to be displayed is an internal diagnostic screen. This is a self-test that shows that all the circuitry of the analyzer is functioning properly. Press EXIT to continue.

The screen should now display the following: "TO PERFORM A CALIBRATION CHECK, PLACE PROBE IN SOURCE HOLDER AND PRESS START." Place probe in holder and continue as directed by the screens.

- If a routine calibration check fails, the screen will display "CALIBRATION CHECK FAILED." Proceed to Section 4.0 to calibrate. (Also see Appendix C, Error Messages.)

3.4 Source Holder Use

- If you are using a C-Trak® OmniProbe®, leave the standard Tc collimator on for calibration.
- If you are using a C-Trak® MiniProbe, remove the collimator for calibration.
- If a sterile drape (sleeve) is on the probe, it must be removed before placing probe in source holder.

Earlier analyzers have a source holder drawer located on the back of the analyzer. Take the check source and place it in the slot to the right end of the holder with the unlabeled side facing the probe. Place the probe in the holder with the nose of the probe against the check source. Use the velcro strap to secure the probe in place. See Figures 18A and 18B for placement of the probe and source.

- The circular depression under the Velcro strap can be used to store the check source.

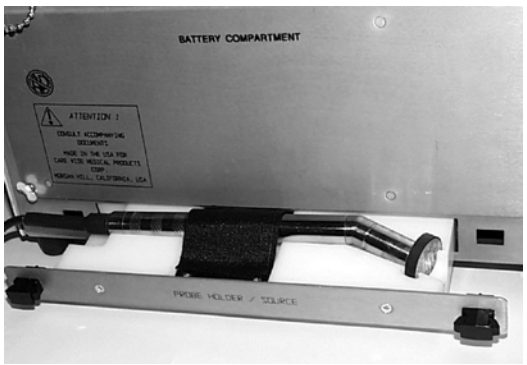


Figure 18 A – Source Holder Drawer

Later analyzers do not have the source drawer; an external source holder is used. Unscrew the two pieces of the source holder and place the source inside with the label facing the foam padding. Screw together. Insert the nose of the probe into the holder so that it "bottoms out" or touches the source. Proceed with calibration steps. When done remove the probe.

Note: If using the OmniProbe®, the collimator may sometimes pull off and stay in the holder. Unscrew the base and remove the collimator with your finger or other soft object.

- Check source may be stored in the holder.

Figure 18 B – External Source Holder

4.0 Performing Calibration

The C-Trak® system will occasionally need to be calibrated to ensure optimal sensitivity. The need will arise if:

- A different probe is selected.
- A new check source is to be used.
- The system fails a routine calibration check.

4.1 Different Probe or Source

If a different probe or source is selected, go to the CONTROL SCREEN and choose PERFORM CALIBRATION. Press START and bring up the PERFORM CALIBRATION screen (Figure 10).

4.2 Failed Calibration Check

If a routine calibration check fails, the screen will display "Calibration Check Failed." Press CALIBRATE and bring up the PERFORM CALIBRATION screen (Figure 10).

4.3 Calibrating

- DO NOT BYPASS WARM UP OF PROBE WHEN DOING A CALIBRATION.

4.3.1

Place the probe in the source holder along with the check source. See Section 3.3 for proper set up.

4.3.2

Press START. The screen will display the calibration process that includes:

- Varying the Bias Voltage applied to the probe, from 500 volts to 900 volts, in 10-volt steps, while searching for the highest observed count rate and then
- Varying the voltage in one-volt steps over a narrower range while, again, searching for the highest observed count rate.

4.3.3

Once found, the corresponding voltage becomes the selected and stored Bias Voltage for that probe. A 20-second count is then taken and stored for future calibration checks.

4.3.4

The screen will display SYSTEM IS CALIBRATED.

4.3.5

Exit through the screens back to HOME SCREEN. Remove the probe from the source holder and the system is ready for use.

5.0 Pre-surgery Set Up

5.1 Before Power Is Turned On

- Install or remove collimator from probe as required. If an OmniProbe® is being used, the standard Technetium collimator is often installed for initial surveys. If a MiniProbe, Technetium probe or Indium probe is being used, the accessory collimator may or may not be installed for initial surveys.
- Connect probe to front panel probe connector.
- Check probe cable for any significant nicks, cuts, or exposed wires.
- Verify that external accessories, if used, are connected properly on the rear panel.

5.2 Turning Power On

- Press MAIN power on the front panel to turn on analyzer.

5.2.1

A five-minute "warm up" period is desirable to stabilize the probe before use; however, you may bypass warm up. If you bypass warm up, the probe may be less sensitive for a few minutes.

5.2.2

Normal operation is designed to utilize the main power supply. The reserve power supply is only designed to provide temporary power if the main power supply fails during a critical operation and the batteries cannot be changed immediately. Turning on either main or reserve power supply automatically turns the other supply off.

5.2.3

The voltage of the power supply in use will be displayed on the screen; e.g., 8.1 vdc. Changing from main to reserve (or the reverse) during use will not affect instrument accuracy.

5.2.4

Turning on the main power supply will automatically begin a diagnostic test cycle to determine if all internal components and voltages are within tolerance. If the instrument fails the DIAGNOSTIC TEST, an error message identifying the failure(s) will appear and the user can acknowledge by choosing the appropriate response on the screen to repeat the test. If the instrument fails the diagnostic tests again, turn OFF the analyzer and contact nuclear medicine or biomedical engineering (or Care Wise), as applicable, for evaluation.

5.2.5

When the instrument successfully completes the DIAGNOSTIC cycle, a message will appear on the screen indicating that the instrument has PASSED the DIAGNOSTIC TEST.

5.3 Battery Check

- Always check batteries before using system.

5.3.1

The main battery supply is provided by six alkaline D-cell batteries; the reserve supply by six alkaline AA-cell batteries. The level of the main battery supply is displayed on the startup screen at the lower left corner, by BATT. The level of the reserve supply is shown by RES - when the reserve supply is turned on. **Note:** The RES voltage displayed when the MAIN supply is on will be incorrect.

5.3.2

Operating battery levels for the main supply must be above 6.9 volts for proper operation. We recommend that fresh D-cell batteries be installed if the main supply is at or below 7.5 volts.

The reserve supply should be at 8.4 volts or above. Check it by turning on the RES supply and then turn it off. It will provide enough power for 10 hours of normal use. The reserve supply should be used only if the main supply becomes too low during a procedure (see below).

5.3.3

When the MAIN battery supply is too low the following occurs:

- The audible alarm is five sound signals in succession (whoop-whoop-whoop-whoop-whoop) repeating at regular intervals.
- The battery symbol at the lower left corner of the screen used during surgery will blink on and off and contain the word "LOW" rather than "OK."
- You will not be able to turn the unit off without removing one or more batteries from the analyzer. If this has occurred, the unit will come back on when you install fresh batteries. If it is not to be used at that time, you should turn it off using the main battery switch.

5.4 Isotope Settings

The SELECT ISOTOPE screen (Figure 12) is used to select the isotope that the C-Trak® system is to set up to detect.

5.4.1

To enter screen, turn the control wheel to bring up the MASTER CONTROL screen (Figure 9). Follow the prompts on the screen to bring up the SELECT ISOTOPE screen.

5.4.2

Select isotope by following the prompts on the screen. Save the selection and then exit the screen.

5.4.3

The EDIT ISOTOPE (Figure 13) screen changes the Window or Threshold settings for a particular isotope.

- The screen is also entered from the MASTER CONTROL screen.

Select the particular value to be changed (Threshold or Window) and edit by following the prompts on the screen. The control wheel changes or edits a selected value. Once editing is done, save the values and exit the screen.

5.4.4

The USER ISOTOPE selection can be used to set up the system for an isotope other than Tc-99m, In-111 or Co-57.

- Note that the sum of the Window and Threshold settings can not be greater than 400 keV.

5.5 Background Test

This test is used to determine if the equipment or the environment is contaminated with radioactive material. The background test should be conducted inside the operating room immediately prior to probe use and logged to establish the baseline or ”normal” amount of radioactivity present.

- Use the same Threshold and Window settings for each Background Test taken. The standard Tc-99m WINDOW settings (Window 40 keV, Threshold 130 keV) are satisfactory.
- Remove or shield all known sources of radioactivity from area. Point the probe up and away from all known sources.
- Perform one or more 10-second counts with probe pointed straight up. Log the results.
- If the results are elevated from the last log entry, decontaminate the probe in accordance with guidelines in manual. If results are still elevated, the environment may be contaminated and the appropriate hospital personnel should be informed.

6.0 Use during Surgery

- Before beginning a procedure, always check the HOME SCREEN to verify that no error messages are present.
- During usage, the HOME SCREEN will be displayed.

6.1 System Adjustments/Changes During Surgery

6.1.1

Select the RATEMETER MULTIPLIER range (x1, x10, x100 or x1000) that provides a full scale range and that allows the ratemeter to read less than full scale during normal use. A lit orange LED indicates the selected multiplier.

6.1.2

Adjust the SPEAKER VOLUME to a comfortable audible level by depressing the UP or DOWN switches marked VOLUME.

6.1.3

To change the counting period for timed counts, go to HOME SCREEN and choose CHANGE COUNT TIME. Increase or decrease the count time by pressing corresponding option. Press EXIT to return to HOME SCREEN.

6.1.4

The HOME SCREEN displays the isotope that the analyzer is configured for. If it is necessary to change the isotope, access MASTER CONTROL screen and SELECT ISOTOPE screen. Make appropriate selection and SAVE.

6.1.5

If Tc-99m is selected, the user has a choice of two THRESHOLD and WINDOW settings. Pressing CHANGE WINDOW will alternate between the settings for Tc-99m Std Window (Threshold 130 keV, Window 40 keV) and Tc-99m Wide Window (Threshold 110 keV, Window 80 keV). The Wide Window setting can be used to accept a greater number of scattered photons, which increases detected radiation but reduces directionality somewhat. The Wide Window setting will be most useful in situations where there is very little radiation (e.g., target tissue has < 25 CPS).

6.2 Cautions

CAUTION: PROBE MUST NOT BE OPERATED IN SURGERY WITHOUT A STERILE DRAPE.

CAUTION: Do not place C-Trak® probe on or near a magnetic drape, pad or mat. The magnetic field can permanently degrade probe components and/or performance.

CAUTION: If the instrument indicates a high background when no radioisotope is present, the sterile disposable drape may be contaminated. Removing the sterile drape from the probe should reduce the background to a normal reading (if no radioisotope is present). Continued indication of radioisotope after the sterile disposable drape has been removed, may indicate the probe body has been contaminated. See SYSTEM DECONTAMINATION.

7.0 Sterile Practices, Cleaning and Disinfecting

The probe is operated while sheathed in a sterile disposable sleeve such as those commonly used with ultrasound probes or laparascopic cameras.

- CAREFULLY FEED PROBE AND CORD INTO SHEATH.
- DO NOT DROP PROBE INTO SHEATH AS THIS PLACES STRESS ON THE CORD.

After the probe is inserted into the end or tip of the sheath, some practitioners place the sheathed tip of the probe into one finger of a surgical glove. They then tie the glove around the body of the probe for further protection and definition of the shape and position of the probe within the sheath.

- The system should be turned off before cleaning or disinfecting. The components of the C-Trak® system may be cleaned and surface disinfected when necessary by wiping down their surfaces with either "Alcohol Wipes" (with 70 percent isopropyl alcohol) or with a lint-free cloth moistened with 70 percent isopropyl alcohol. This method is satisfactory for cleaning the surfaces of the analyzer control unit, the detector probe and its cables, the footswitch and cable assembly, and the printer with its cable.

IMPORTANT NOTE: The OmniProbe®'s collimator MUST be removed when cleaning or sterilizing! Both the inside and outside surfaces must be cleaned and/or sterilized. For cleaning, Care Wise recommends using a bottle brush for cleaning inside the collimator. For sterilization, Care Wise recommends removal of the collimator and sterilizing it separately, alongside of the OmniProbe® device.

- The analyzer control unit must not be sterilized or immersed. Never immerse the connector ends of the cables for the probe, the footswitch, or printer in liquid.

Steam or dry heat sterilization will damage the detector probe and cable, void the warranty, and could result in injury to the operator or patient.

8.0 System Decontamination

The probe could be contaminated with radioactive isotope if the instrument indicates an increase in background counts in the NORMAL OPERATING MODE, with no radioisotope near the probe. The system can be tested for radioisotope contamination by doing a background test (Section 5.5). If the probe is found to be contaminated, use the following procedure to remove radioactive contamination. Also, check with your nuclear medicine or biomedical engineering departments, as applicable.

8.1 Decontamination Steps

8.1.1

Remove the sterile cover from the probe – the background should return to normal. If the system still indicates a high background, proceed to the next step.

8.1.2

Turn the system off.

8.1.3

Use a disposable pan, vessel, etc, to contain the liquid required to complete the cleaning process. The liquid, disposal wipes, and any other material that will contact the liquids used in the decontamination process must be assumed to be radioactive. These materials and liquids must be handled and disposed of as per your institution's license agreements with state and federal regulatory agencies. Consult with your radiation safety officer for guidance.

8.1.4

Use a commercially available decontaminating product to clean the probe. Rinse the probe several times with distilled water.

8.1.5

Dry the probe thoroughly with a disposable wipe. It is extremely unlikely that the probe cable will become contaminated; however, if it does, the same practice can be followed as with the probe, being careful not to immerse the connector end of the cable in liquid.

8.1.6

Turn on the C-Trak® system and wait until the system returns to the normal operating mode. If the system is still indicating a high background, turn the system off and repeat the steps above. If the system still indicates a high background, contact nuclear medicine or biomedical engineering for evaluation. The probe may have been damaged.

9.0 Safety Considerations

9.1 Current Overload

The current overload indicator signals excessive current flow to the probe. If the current OVERLOAD indicator is on, the system will not operate until it is reset. Before resetting the system, inspect all external wiring, connectors, etc, for obvious damage. If no obvious defects are found refer to Section 11.5 and/or Appendix C for corrective action.

9.2 Power Supply Requirements

9.2.1

The system is designed and manufactured to operate with D-cell disposable alkaline batteries in the MAIN power supply and AA-cell disposable alkaline batteries in the RESERVE power supply.

9.2.2

Do not attempt to operate the instrument or printer with any type of AC powered "Battery Eliminator" or to connect the instrument to an AC power line through any type device. Connecting the instrument to the AC power line will void the warranty and could result in serious damage to the patient, operator and/or instrument.

- Do not attempt to disassemble or otherwise service the probe or analyzer unit. THERE ARE NO USER SERVICEABLE PARTS.

DISASSEMBLY VOIDS THE WARRANTY AND TRANSFERS ALL CONTINGENT LIABILITY TO THE INDIVIDUAL AND INSTITUTION INVOLVED.

9.3 Accessory Collimator

The accessory collimator, when used, must be firmly attached to the probe to avoid injury to the operator or patient. When attaching it, make sure the air hole in the side or nose (depending on collimator) is not covered. The collimator will click firmly in place when installed properly.

9.4 Radioactive Concerns

All radioactive isotopes and/or material, drapes, liquids, cleaning materials, etc, that comes in contact with a radioisotope, or item that is contaminated with a radioisotope, must be handled as per your institution's radiation rules and regulations. Consult with your institution's Radiation Safety Officer for guidance concerning the use and disposal of radioactive material.

9.5 Use of Electrosurgical Devices

Electrosurgical and other electrocautery devices can emit excess electromagnetic "noise." This "noise" may cause the C-Trak® analyzer to record false counts if these devices are used to cut or cauterize concurrent with the probe's use in surgical exploration.

DANGER: The C-Trak® system is not intended for use in the presence of flammable anesthetics or other explosive gases. There is a risk of explosion if the System is used in the presence of flammable anesthetics.

CAUTION: Do not place C-Trak® probe on or near a magnetic instrument pad (or mat). The magnetic field can permanently degrade probe components and/or performance.

10.0 Use of Optional Accessories

10.1 LED Repeater

The repeater repeats the timed counts and count rates displayed by the analyzer HOME SCREEN and can be placed in full view of the user during surgery.

10.1.1

The repeater can be easily affixed to an IV pole and moved to the most convenient and easily seen location.

10.1.2

The repeater is provided with a ten-foot cable that plugs into the "Display" receptacle on the rear panel.

10.1.3

The small green lights on the faceplate, when lit, indicate whether it is displaying count rate (in counts per second) or is in the process of taking a timed count. The small red light, when lit, indicates the batteries are low (see below).

10.1.4

The repeater should not be immersed or sterilized. Cleaning can be done by wiping the surface with a disinfectant or alcohol wipe.

10.1.5

To replace the batteries, place the repeater "face down" on a flat surface, unscrew the four screws and lift off the back. Replace batteries (uses six AA-cell batteries). Fit back carefully to front and tighten screws. Do not over tighten.

- **Partially tighten opposite corners and alternate tightening until screws are secured.**

10.2 Lechner Collimator

The Lechner collimator is a special purpose collimator designed for certain conditions of high radiation levels from tissues of no clinical interest (nonspecific uptake or background). The collimating section of the nose of the collimator has a smaller inner diameter and greater depth than the Standard Technetium collimator. The outer diameter, however, is the same as the Standard Technetium collimator.

By replacing the Standard collimator with the Lechner model, the OmniProbe® becomes more directional but less sensitive. The overall outer diameter of the OmniProbe® nose (with either collimator installed) is the same. This can be a major advantage in certain types of clinical cases.

Other special collimators can be made available by special order. Call Care Wise on +1-813-626-6848 (US & Canada) +44 1273 497600 (Europe & Worldwide) for information and advice as needed.

10.3 Blocking Plate

The C-Trak® blocking plate is a hand-held Tungsten alloy plate. Its dimensions are 3" x 3 -1/2" x 1/8" thick.

The user can selectively block radiation from known areas of high radioactive uptake. It is another tool (like special collimators) allowing the user to better cope with high radiation levels from tissues of no clinical interest (nonspecific uptake or background).

10.4 Indium Shield Assembly

The Indium shield assembly converts the C-Trak OmniProbe® from a probe with shielding and collimation optimized for use with radioisotope Tc-99m to a probe optimized for use with the higher energy radioisotope In-111.

10.4.1

To install the shield, disconnect cable from the OmniProbe® and remove the standard collimator already on the probe.

10.4.2

Start from the cable-connector end of the probe and, with the protuberance end of the shield facing the probe and the protuberance on top, slide the shield over the probe shaft.

- **Do not insert the probe all the way into the shield – leave about 1 mm between the end of the shield and nose bend.**

10.4.3

Line up the small hole in the Indium collimator so that it is facing away from the probe bend and is on top when holding the probe shaft horizontal with the nose bend facing down.

10.4.4

Slide the Indium collimator onto the probe nose. You may need to "wiggle" it in place. Line up the hole in the collimator with the shield protuberance and push together.

The probe is now ready for use.

11.0 Technical Specifications

11.1 Power

Main power supply consists of 6 alkaline, D-cell long shelf life batteries, contained in the analyzer.

Reserve power supply consists of 6 alkaline, AA-cell long shelf life batteries, contained in the analyzer.

Both Main and Reserve batteries are accessible from the instrument's rear panel. No tools are required to change the batteries.

All internal voltages are closely regulated to within ±0.1 vdc. Battery voltage will not affect instrument operation or accuracy until the battery voltage is reduced to below 6.9 vdc (end of useful battery life).

Diagnostic circuits automatically monitor the voltage of both internal power supplies (main and reserve). If the voltage from the MAIN power supply decreases to less than 7.0 vdc, a warning will begin to blink on the LCD display. Also, an audible tone will be heard every 10 - 15 seconds until the instrument is switched to the RESERVE power supply or the batteries are replaced and the internal power supply voltages are above 7.0 vdc. The same warning signals will be displayed if the RESERVE power supply decreases to less than 8.0 vdc.

A stable high voltage supply provides the bias voltage required for proper operation of the probe. The bias voltage can be adjusted to meet each probe's requirements during calibration. Probes require between 500 and 900 vdc bias voltage for proper operation.

11.2 LCD Display

320 x 240 pixels monochrome type

5.125" (130mm) wide x 3" (76mm) high

11.3 Ratemeter

FOUR RANGES:

Selectable from touch sensitive range multiplier buttons on the front panel. Ranges are:

x1 = 0 – 30 CPS
x10 = 0 – 300 CPS
x100 = 0 – 3,000 CPS
x1000 = 0 – 30,000 CPS

RATEMETER DISPLAY:

A high torque taut-band analog meter with a 0 - 30 scale. Scale length 4.22" (107 mm).

Accuracy ± 2% of full scale.

RATEMETER LINEARITY:

± 5% of full-scale

RATEMETER RESPONSE:

Automatically optimized for each range and does not require adjustment.

11.4 Probe Connector

Series "MHV" coaxial connector for ALL probes (detectors).

11.5 Probe Overload Indicator

The red LED overload indicator will light and the bias voltage supplied to the probe will be reduced to near zero if the probe current exceeds 10 micro amps. The INTERNAL DIAGNOSTIC screen (Figure 5) will replace the screen in use and will display "Probe Fault: Failed." (See Appendix C for corrective action. If corrective action does not work and the warning is still present, contact nuclear medicine or biomedical engineering or Care Wise on +1-813-626-6848 (US & Canada) +44 1273 497600 (Europe & Worldwide) for evaluation.)

This is a safety feature of the C-Trak® system. Ten micro amps is the international standard for the maximum allowable leakage current from a medical device operating off of external power which contacts a patient's body during use.

11.6 Rear Panel Connectors

PHA out (for pulse-height analyzer): BNC coaxial connector

RS-232/printer output: 9-pin "SUB-D" female

External LED Display: 9-pin"SUB-D" male

Remote footswitch: 3-pin female Switchcraft SL173F

11.7 Size

12.3" (312 mm) long x 10" (254 mm) deep x 7" (178 mm) high.

11.8 Weight

≈10 lbs (≈4.5 kg) including full battery complement (without detector).

11.9 Housing

Aluminum with moisture resistant touch sensitive front panel.

11.10 Finish

Aluminum cover, back panels and chassis with catalyzed polyurethane enamel coating; front panel is laminated with silk-screening beneath top polycarbonate layer.

11.11 Environmental

Temp 10° C - 40° C, Hum 30% - 75%

11.0 Technical Specifications (continued)

11.12 Compliance

CE mark certified

Meets requirements of US Food and Drug Administration and Medical Device Directive of the European Union.

EN 60601-1 (3rd Ed) and 60601-1-2 certified.

11.13 Serial Numbers

The serial number of the analyzer is located on the back. The serial number for the probe is located in the vicinity of the cable connection.

12.0 International Symbols

12.1 Front Panel

Loudspeaker

Start Symbol

High Voltage

12.2 Rear Panel

Information, Consult Accompanying Documents (User's Guide)

Printer

Equipment not suitable for use in the presence of a flammable mixture with air or with oxygen or nitrous oxide

Medical – General Medical Equipment as to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1:2003, CAN/CSA C22.2 No. 601.1:2005, ANSI/AAMI ES60601-1:2005, CAN/CSA-C22.2 No. 60601-1:2008 <48ZK>

Conformity with the MDD has been confirmed and approved by the Notified Body UL International (UK) Ltd. Registration Number: 0843

Degree of protection against electric shock:
Type B Applied Part (OmniProbe® Family of Probes)

Appendix A

C-Trak® Quick Reference for Surgical Use

- Check that probe cable is free of any nicks, cuts, or exposed wires. Connect probe, then turn power on.
- Check calibration at least once a week if used weekly or before each surgical use if used less often.
- Take background test to ensure probe is free of contamination.
- Set Ratemeter at desired multiplier range (x1, x10, x100, x1000) based on the expected level of activity.
- "x10" is often a good setting for the initial survey. If the analog meter is "pegged" (needle remaining at 30 or 0) when probe is scanning an area of interest, change the range. Change to a higher range (x100) if pegged at 30 or a lower range (x1) if pegged at 0.
- Check VOLUME setting to ensure a comfortable level.
- Look at the HOME SCREEN - are the correct isotope, window and threshold selected?
- Use the probe to locate the area of greatest radiation uptake before making the first incision.
- In sentinel node procedures, always remain conscious of the location of the injection site in order to differentiate between very high levels of radiation coming from the injection site and radiation coming from the desired tissue; e.g., sentinel lymph node itself. It can be helpful to mark the patient's skin to show the boundary of the very high level radiation coming from tissue immediately surrounding the injection site.
- Move the probe slowly and avoid jerky movements. With experience the user will develop a "feel" for the appropriate speed.
- Detected count rates drop with the square of the distance from tissue being viewed. Stay very close to the tissue plane. While performing the initial survey, be careful not to push the probe into the skin while moving it, as this will also move the skin relative to the lymphatics.
- Take a 10-second count for the ex vivo specimen(s) and for the cavity (background). This will establish whether all significantly radioactive tissue has been removed.
- Every 18 months, replace the 5 µCi Co-57 source. You may purchase a check source through Care Wise (Part number CSC).

Call Care Wise on +1-813-626-6848 (US & Canada)
+44 1273 497600 (Europe & Worldwide) with any inquiry.

Appendix B

Troubleshooting Q & A

I push main power "ON" but nothing happens. What's wrong?

1. Check that the batteries are installed properly (check the polarity & contacts). Try again.
2. Replace the 6 each "D" batteries. Try again.
3. Still won't "turn on?" Call Care Wise.

I'm not getting counts

1. Check that cable connectors are "turned and locked" in place on the analyzer and "pushed-in and locked" on the probe. If not, correct, and try again.
2. Check that analyzer has proper Window and Threshold settings for isotope in use. If not, correct and re-try.
3. Check that you get counts with Co-57 source held against nose of probe. If yes, then problem may be with radiopharmaceutical administration or distribution.
4. Check calibration. If OK, try using again. If not OK, recalibrate. If no counts during calibration process, probe may be damaged. Call Care Wise.

NOTE: During calibration check, or re-calibration, Nose of OmniProbe, with Collimator installed, must be centered on and flush against bare side of Co-57 Check Source. Source must be less than two years old. (If using MiniProbe, Collimator must be off).

The red probe overload light is on

1. "PROBE FAULT: FAILED" will also be displayed on the Self-Test screen.
2. Turn power OFF, wait a few seconds to allow system to reset. Turn system ON. If both "FAILED" and OVERLOAD LIGHT are no longer displayed, proceed with use of system.
3. If system still shows "FAILED" and/or OVERLOAD LIGHT, turn system off. Disconnect probe. Turn analyzer ON. If the overload/fault displays are not now activated, the problem is likely a damaged probe or probe cable.

   Before reconnecting probe to analyzer, inspect surfaces and both ends of cable/probe connections and probe connector on analyzer for damage. If visible damage is present, contact responsible hospital department or Care Wise.
4. If no visible damage, reconnect probe and turn system ON. If overload/fault displays do not recur, proceed with use of system. If they do recur, turn system OFF and contact Care Wise.

I am getting counts – for no reason

1. I get counts with analog meter on "X1" and no source present.

   Likely due to stray radiation or contaminated area – Clean area and retest.
2. I get counts when I shake the probe or wiggle probe cable.

   Likely due to damaged probe or probe cable – Call Care Wise.
3. I'm getting counts and the probe is not connected – Call Care Wise.

Analyzer is making sounds – Whoop!, Whoop!, Whoop! (five times)

1. Five whoops is the low battery alarm. If batteries are low the LOW battery symbol should be displayed at the lower right corner of the HOME SCREEN.
2. Check battery level. If less than 7.0 Volts, switch to RES. If sound stops, sound was low battery alarm.
3. At first opportunity check both MAIN and RES batteries. MAIN should be at least 7.5 Volts at start of case; RES should be at least 8.5 Volts (must have RES power button "on" to check RES). Replace all low batteries.
4. If Batteries less than 6.9 Volts, unit may not shut off. Open battery compartment and remove one D-cell battery (or one AA battery, if RES "on"). Unit will turn off.
5. If battery alarm stays on with good fresh batteries, Call Care Wise.

When should I perform "QC CHECK" (termed "CALIBRATION CHECK")?

1. If the system is used every day, check before use once a week (allowing time for tech support, if needed).
2. If the system is used less often, check before using (allowing time for tech support, if needed).

How do I get the sound louder?

Check out Figure 1, item 6, in the manual. It shows the location of the Volume Control. The bar on the right of the LCD screen represents the sound level.

The power won't turn off!

Replace the batteries with fresh ones. On rare occasions when the battery voltage is lower than 7.0 volts, the system will not allow you to turn itself off using the Power On/Off button. Removing a battery will turn the system off; replacing it will turn itself back on.

If changing the batteries does not fix the problem – call Care Wise.

Appendix C

Error Messages

Screen: CALIBRATION CHECK

The following message may be displayed during calibration check:

> **CALIBRATION CHECK FAILED**

Corrective Action:

- Assure that the probe is configured for checking calibration; i.e., the standard collimator is installed (if it is an OmniProbe) or the collimator is removed (if it is a MiniProbe).
- Assure that calibration check source is properly positioned at the nose of the probe (the same way it was positioned during system calibration). Try again to check calibration.
- If the system fails calibration check again, turn the control wheel to bring up the MASTER CONTROL screen, select PERFORM CALIBRATION and recalibrate the system.

Screen: CALIBRATION

The following message may be displayed when you exit at the completion of calibration:

> **SYSTEM IS CALIBRATED**
>
> **Your calibration source may need replacing soon**

- The system is calibrated and ready for use – even if this message is displayed. Exit the calibration screen and return to the home screen and continue as applicable.
- As soon as possible, perform the Corrective Action below.

Corrective Action:

- Assure that probe is configured for calibration; i.e., the standard collimator is installed (if it is an OmniProbe) or the collimator is removed (if it is a MiniProbe).
- Assure that the check source is properly positioned at the nose of the probe.

Try again to calibrate:

- If message is displayed again, contact Care Wise for information on purchasing a fresh 5.0 µCi Co57 source.

Screen: CALIBRATION

While performing a calibration, the displayed word "CALIBRATING" is replaced with the following.

> **CALIBRATION FAILED**
>
> **Please Recalibrate. If this recurs, contact Care Wise**

Corrective Action:

- Assure the probe is configured for calibration; i.e., the standard collimator is installed (if it is an OmniProbe) or the collimator is removed (if it is a MiniProbe).
- Assure that the check source is properly positioned at the nose of the probe.

Try again to calibrate.

- Observe the counts-per-second (cps) displayed during the first calibration "run" of voltages from 500 Volts to 900 Volts.
- If the highest cps values are around or below 500 cps, you may have a low calibration check source.
- Contact your nuclear medicine department and try to obtain a source that is at least 1.0 µCi and try to calibrate with it. If successful, you may use the system.
- If the system will not calibrate with a source of 1.0 µCi or more, contact Care Wise.

Screen: HOME SCREEN

During the use of the system, the "OK" in the battery symbol at the lower right corner of the HOME SCREEN (and others) may change to a flashing "LOW."

> **LOW**

Corrective Action:

- Replace batteries in the Main Battery supply with fresh D-cells.
- Also, check the RESERVE battery level by pressing RES. If they are less than 8.5 Volts, replace them.

Appendix C (continued)

Screen: INTERNAL DIAGNOSTIC

During the initial system set up or during use, an error could be identified by the system and the screen you are using replaced with the INTERNAL DIAGNOSTIC screen. One or more "FAILED" messages may appear on the screen. Only Date/Time and Probe Fault can be corrected by the user. If any other item displays 'FAILED," call Care Wise.

SYSTEM FAILURE

Contact Care Wise

XXXXXX : ok
XXXXXX : ok
DATE/TIME : FAILED
XXXXXX : ok
XXXXXX : ok
PROBE FAULT: FAILED
XXXXXX : ok
XXXXXX : ok

Corrective Action – DATE/TIME:

- Turn control wheel and bring up MASTER CONTROL screen. Select FACTORY MENU and proceed to set date and time. Save changes and exit.
- Turn the system off then back on. Return to INTERNAL DIAGNOSTIC screen. If the DATE/TIME condition is "OK," continue as applicable.
- If the 'FAILED" message is still displayed, contact Care Wise.

Corrective Action – PROBE FAULT

- If the current at the probe connector is more than 10 µ amps, the power to the connector and the probe (if installed) will be turned off and the red overload light will be on.
- The INTERNAL DIAGNOSTIC screen will replace the screen in use and Probe Fault will display "FAILED."
- Turn the power off. Wait 10 seconds. Turn power back on. The system should reset and the overload light will be off and "FAILED" replaced with "OK."
- If all items are "OK," return to the screen you were previously using and continue.
- If the problem is not corrected, call Care Wise.

Appendix D

Probe Handling

Treat the probe as you would any expensive, delicate instrument.
Inside the probe are crystals and a glass photomultiplier tube.
If the probe is dropped or hit against something hard, it can break.

PLEASE HANDLE CAREFULLY

Figure 27 – Detaching the C-Trak® Cable

(1) Grasp cable connector by release sleeve.

(2) Gently pull release sleeve away from probe as shown below. Cable will release.

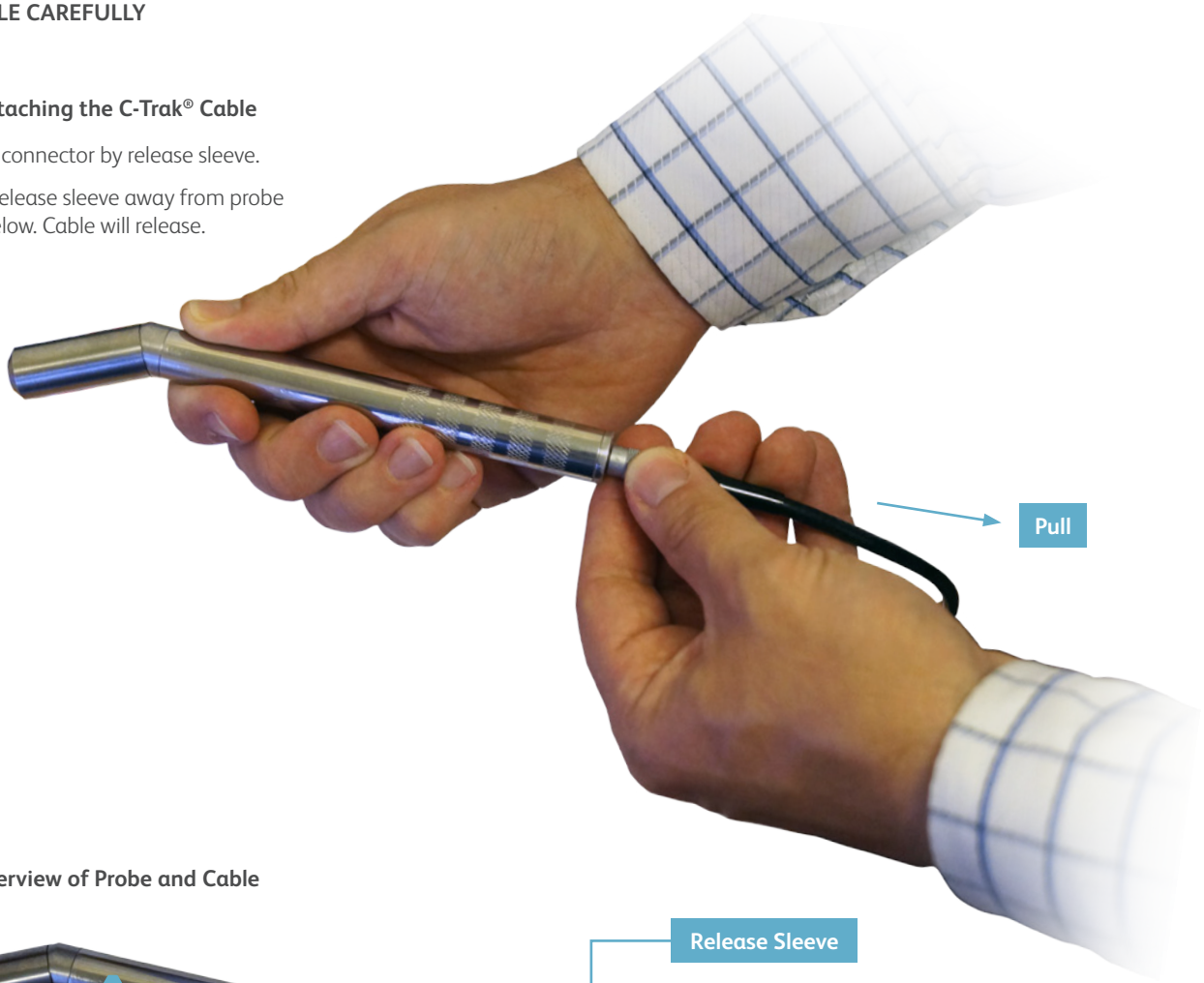
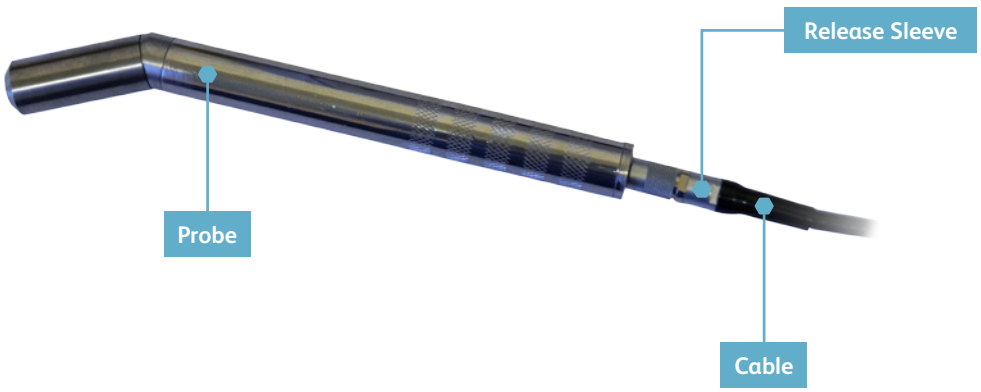


Figure 26 – Overview of Probe and Cable



Appendix E

USE OF C-Trak® OmniProbe®-EL Probe

1.0 Selecting OmniProbe®-EL Probe

- OmniProbe®-EL Probe (EndoProbe) is shown as “ENDO” on Analyzer LCD screens.

1.1

Turn power on.

1.2

Rotate Control Wheel on right side on Analyzer to bring up Master Control Screen.

1.3

Use SELECT FIELD to select the SELECT PROBE screen, and press START. This brings up the SELECT PROBE Screen.

- Use SELECT FIELD to select the ENDO probe, then press SAVE CHANGES.
- Press EXIT. The Master Control Screen will appear.

2.0 Select Isotope Threshold and Window Settings

- If the clinical isotope to be used is Tc-99m, use of the Tc-99m Wide Window is recommended (Threshold of 110 keV, and Window of 80 keV). If the surgeon elects to use these settings, carry out the following steps:

2.1

Start from the Master Control screen (see 1.3 above).

2.2

Use SELECT FIELD to select the SELECT ISOTOPE screen, and press START. This brings up the SELECT ISOTOPE screen.

2.3

Use SELECT FIELD to select Tc-99m Wide Window, and press SAVE CHANGES. Press EXIT. The Master Control screen will appear.

2.4

Press EXIT, the Home screen will appear. The Analyzer is now set up to use the OmniProbeEL.

- For use with other isotopes, please refer to Product Manual (Para. 5.4, “Isotope Settings.”)

3.0 Calibration

The Analyzer must always be calibrated for use with the specific probe that is to be used with it. With Firmware Version 2.08 or higher, the Analyzer will retain calibration for a specific probe once performed and saved. For Example, the User may have the Analyzer calibrated for an OmniProbe, and for an OmniProbe®-EL. Once both calibration processes are carried out, the Analyzer will retain them. Selecting the probe to be used, as described under 1.0 above, will activate the correct Bias Voltage for that probe.

3.1

With the ENDO selected, the calibration process is essentially the same as that for an OmniProbe or a MiniProbe. (Refer to Product Manual.)

- A one-inch diameter disc Cobalt 57 source is used to calibrate the OmniProbe®-EL, as is done with the OmniProbe® and the MiniProbe.
- The check source holder with the OmniProbe®-EL holder insert should be used with the OmniProbe®-EL. The OmniProbeEL holder insert should be fully inserted into the source holder. (**Note:** 90o Omni-EL uses a different Source Holder).

3.2

Place the source holder, with probe, on a level surface so that the flat side of the holder rests on the surface as well as the handle of the probe. Be sure the probe is pressed firmly against the check source during calibration. Have someone assist, if necessary.

3.3

With probe and source positioned, the Calibration Process and the System Check Process are carried out in the same way as with the OmniProbe and the MiniProbe. (Refer to Product Manual, Para. 4.0 “Performing Calibration.”)

3.4

When done, slowly remove the probe from the holder, to avoid allowing probe to strike any hard surface. Check source may be stored in the holder.

Appendix E (continued)

4.0 Sterile Practices, Cleaning and Disinfecting

CAUTION: Probe must not be used in minimally invasive or "Laparascopic" surgery when inserted through a trocar sheath or cannula, without first being cleaned and then sterilized (with probe cable removed).

See Par. 4.5 below if OmniProbe®-EL is to be used in open surgical procedures, without being introduced through a trocar sheath or cannula.

4.1 Cleaning

External surfaces of OmniProbe®-EL Probe (with cable removed) must be properly cleaned prior to sterilization and post-sterilization attachment of sterile drape that covers handle and cable.

NOTE: Neither water nor any other liquid may be allowed to be present within the cable connector at the distal end (base) of the probe handle when cable is installed therein. Liquid present within said connector may cause electrical short-circuits rendering probe unusable; connector must be completely dry during clinical use. Said connector shall always be enclosed within the sterile drape covering handle and cable during clinical use. (If the STERIS sterilization process is used, said connector must be completely dry before cable is re-installed into probe.)

The following products/processes are recommended by Care Wise for the cleaning/sterilization of our products.

1. Prepare an enzymatic detergent (Klenzyme®) according to manufacturer's recommendations,
2. Using a clean, absorbent cloth or sponge soaked with Klenzyme® (prepared following manufacturer's instructions), thoroughly dampen and "soak" all external probe surfaces (with cable removed), except for the surfaces of the cable connector at the distal end (base) of the probe handle.
3. After allowing the detergent (Klenzyme®) to stay on probe surfaces for five minutes, remove detergent using clean absorbent cloth soaked in clean tap water.
4. Prepare a second cleaning detergent (Manu-Klenz®) according to the manufacturer's recommendations,
5. Thoroughly clean all external probe surfaces, except for said surfaces of the cable connector, by: a) using a clean, absorbent cloth or sponge soaked with Manu-Klenz® (prepared following manufacturer's instructions), and b) using a hand-held soft bristle brush wetted with Manu-Klenz® to brush surfaces in a back-and-forth motion.
6. Remove Manu-Klenz using clean absorbent cloth soaked in clean tap water. Repeat as necessary.
7. Probe (with cable removed) is now ready for sterilization.

(**NOTE:** Klenzyme and Manu-Klenz are provided by STERIS Corp, of Mentor, Ohio, USA).

4.2 Sterilization

The probe, with cable removed, can be sterilized by the hospital using one of the following methods:

1. A Full Cycle of the STERRAD® 100S Sterilizer. (Equipment is available from Advanced Sterilization Products, a Johnson & Johnson company, and a division of Ethicon, Inc., Irvine, CA, USA)
2. Ethylene Oxide Sterilization (as validated by Nelson Laboratories, Inc., Salt Lake City, UT, USA).

Preconditioning Parameters:

Temperature	54 ± 2°C
Relative humidity:	70 ± 5%
Vacuum set point:	1.3 psia
Steam partial pressure	2.18 psia
Preconditioning set point:	2.8 psia
Preconditioning time:	1 hour

Sterilization Parameters

Temperature	54 ± 2°C
Relative humidity:	70 ± 5%
Pressure set point:	9.3 psia
Ethylene oxide concentration	725 ± 25 mg/L
Gas exposure time (full cycle)	2 hours
Aeration time (full cycle)	12 hours
Aeration temperature:	51 – 59 °C

NOTE: Sterilization other than that described above could damage the probe and cable, voids the warranty, and could result in injury to the operator or patient

- Cable and probe handle must be covered by a sterile drape.

4.3

The probe cable may be used in a sterile field after a sterile drape is placed over cable and secured in place on handle of the Sterilized probe. (An acceptable drape is Advanced Medical Designs, Inc, Marietta GA, "Universal Camera and Laser Drape With Semi-opaque Closure, 5 inches wide by 96 inches long [AMD Part 04-CC216], or equivalent)

Drape requirements are:

- Open at the nose (small opening) as well as the rear end.
- Has either an elastic nose or a nose with tapes and/or rubber bands.
- Is 5-6 inches wide and 96 inches long.

4.4

Suggested installation sequence is as follows.

Appendix E (continued)

4.4.1

A professional in the sterile field (i.e., scrub nurse) holds the sterile OmniProbe®-EL and the sterile drape.

4.4.2

A professional outside the sterile field (i.e., circulating nurse) holds the cable.

4.4.3

The scrub nurse inserts the probe handle into the small opening of the drape and passes the "rear" end of the drape (without pulling it out to its full length) to the circulating nurse.

4.4.4

The circulating nurse takes the "rear" end of the drape in one hand and the cable in the other hand, reaches into the unextended drape with the cable and inserts the cable connector into the OmniProbe®-EL connector.

4.4.5

The scrub nurse closes the drape on the probe handle with the tape or rubber bands supplied with the drape.

4.4.6

The circulating nurse pulls the drape up the cable to its full length, connects the cable to the analyzer.

4.5.

The components of the C-Trak® system other than the OmniProbe®-EL may be cleaned and surface disinfected when necessary by wiping down their surfaces with either "Alcohol Wipes" (with 70 percent isopropyl alcohol) or with a lint-free clothe moistened with 70 percent isopropyl alcohol. This method is satisfactory for cleaning the surfaces of the analyzer control unit, the detector probe (other than OmniProbe®-EL) and its cables, the footswitch and cable assembly, and the printer with its cable.

- The analyzer control unit must not be sterilized or immersed.

IMPORTANT NOTE: The OmniProbe®'s collimator MUST be removed when cleaning or sterilizing! Both the inside and outside surfaces must be cleaned and/or sterilized. For cleaning, Care Wise recommends using a bottle brush for cleaning inside the collimator. For sterilization, Care Wise recommends removal of the collimator and sterilizing it separately, alongside of the OmniProbe® device.

4.6.

NOTE: If OmniProbe®-EL is to be used in "Open Surgery," without being passed through a trocar sheath or cannula, then the same sterile practices used with C-Trak® OmniProbes, involving a sterile drape covering probe and cable, may be used with the C-Trak® OmniProbe®-EL (See Para. 7.0, p.23). Probe sterilization shall not then be required.

Appendix F

Use of C-Trak® OmniProbe® PET Device

CAUTION: Handle the OmniProbe® PET device by its body not the cable. Handling by the cable will place undue stress on the cable connection, and possibly render the device inoperative.

1.0 Selecting OmniProbe® PET Device ("PET Probe")

- **PET Probe is shown as "FDG" on Analyzer LCD screens.**

1.1

Turn power on.

1.2

Rotate Control Wheel on right side on Analyzer to bring up Master Control Screen.

1.3

Use SELECT FIELD to select the SELECT PROBE screen, and press START. This brings up the SELECT PROBE Screen.

- Use SELECT FIELD to select the "FDG" (PET) Probe, then press SAVE CHANGES.
- Press EXIT. The Master Control Screen will appear.

2.0 Select Isotope Threshold and Window Settings

2.1

Start from the Master Control screen (see 1.3 above).

2.2

Use SELECT FIELD to select the SELECT ISOTOPE screen, and press START. This brings up the SELECT ISOTOPE screen.

2.3

Use SELECT FIELD to select "FDG (or Na-22)", and press SAVE CHANGES. Press EXIT. The Master Control screen will appear.

2.4

Press EXIT, the Home screen will appear. The Analyzer is now set up to use the PET Probe.

3.0 Calibration

The Analyzer must always be calibrated for use with the specific probe that is to be used with it. The Analyzer will only work with the OmniProbe® PET Device ("PET Probe") with Firmware Version 2.08 or higher. It will retain calibration for a specific probe once performed and saved. For Example, the User may have the Analyzer calibrated for an OmniProbe®, and for a PET Probe. Once both calibration processes are carried out, the Analyzer will retain them. Selecting the probe to be used, as described under 1.0 above, will activate the correct Bias Voltage for that probe.

3.1

With FDG selected, the calibration process is essentially the same as that for an OmniProbe® or a MiniProbe. (Refer to Product Manual.)

- A Sodium 22 (Na-22) Source (one-inch diameter disc) is used to calibrate a PET Probe. The Na-22 annihilation radiation photon peak is at 511 keV, the same energy as FDGs annihilation radiation photons.

3.2

Place the Na-22 Source in the PET Source Holder, label down (larger inside probe diameter for a PET Probe). Then place the PET Probe in the Source Holder, as with the OmniProbe® or MiniProbe, flush against the Na-22 Source.

3.3

With probe and source positioned, the Calibration Process and the System Check Process are carried out in the same way as with the OmniProbe and the MiniProbe. (Refer to Product Manual, Para. 4.0 "Performing Calibration.")

3.4

When done, remove the Probe from the Source Holder, and store the Source Holder (with Na-22 Source inside) within the System Case. The System (Probe and Analyzer) is now set up and ready for use.

4.0 Cable and Probe must be covered by a sterile drape.

The Probe is operated while Probe and Cable are sheathed in a sterile disposable sleeve such as those commonly used with ultrasound probes or laparoscopic cameras, as well as with the OmniProbes and MiniProbes.

- Carefully feed probe and cord into sheath.
- Do not drop probe into sheath as this places stress on the cord.

After the probe is inserted into the end or tip of the sheath, some practitioners place the sheathed tip of the probe into one finger of a surgical glove. They then tie the glove around the body of the probe for further protection and definition of the shape and position of the probe within the sheath.

Appendix G

Proof of Cleaning Statement

(Must be included with any C-Trak® Device/System return)

RMA Number: _____ Date: _____

Purchase Order Number: _____

Serial Number(s) and Reason(s) for return:

S/N-1 _____ REASON-1 _____

S/N-2 _____ REASON-2 _____

S/N-3 _____ REASON-3 _____

S/N-4 _____ REASON-4 _____

S/N-5 _____ REASON-5 _____

This "Proof of Cleaning Statement" is a safety requirement. Its purpose is to assure that the item(s) being returned for evaluation/repair/maintenance pose no biological threat to any personnel that may be exposed to said product.

A thorough cleaning with 70% denatured alcohol or an enzymatic detergent (such as Klenzyme, Manu-Klenz or similar product) will suffice.

If you are returning an OmniProbe® device with a collimator, the collimator must be removed and cleaned thoroughly, inside and outside along with the probe body. No residue is to remain on the probe or collimator surfaces.

Improperly cleaned product may be returned to the customer at their expense or incur a $150 cleaning charge.

If there are questions on how to properly clean the equipment, please refer to your Product Manual or call Care Wise for instructions.

I attest that the above cleaning procedure has been completed and that the item(s) being returned is/are not contaminated and pose(s) no biohazard threat to personnel.

Signature: _____

Date: _____

Title: _____

Appendix H

Care Wise Product List

C-Trak® Systems and Components	Product Code
1. C-Trak® Galaxy standard systems	
a. With OmniProbe® standard device and standard Technetium collimator	GDBS
b. With OmniProbe® EL device	GSLS
c. With OmniProbe® PET device	GSPT
2. C-Trak® Galaxy bundled systems	
a. With OmniProbe® standard device, standard Technetium and Lechner Collimator	GSCS
b. With OmniProbe® standard device, standard Technetium collimator and OmniProbe® EL device	GSES
c. With OmniProbe® standard device, standard Technetium collimator and OmniProbe® PET device	GSSP
d. To add any additional items use the product code and discount its list price by 10%	
3. Component Parts	
a. C-Trak® OmniProbe®	
Standard device with snap on Technetium Collimator (Angled)	OPB
Standard device with snap on Technetium Collimator (Straight)	OPS
Indium handle shield and Indium collimator	OPSC
EL device straight	SEL
EL device 20°	AEL
EL device 90°	NEL
PET device	OPT
b. C-Trak® Analyzer Galaxy	CW4000
Automatic (Refurbished)	CW3000 (R)
Dual [Refurbished – Available in US only]	CW2200R
4. Accessories	
a. C-Trak® OmniProbe® collimators	
Standard	OPTC
Lechner (5mm opening)	OPCL
b. Galaxy Printer	GP
c. Galaxy Power Cable	GPC
d. Power Supply (Brick)	GPS
e. Power Adaptor – International (by country)	GPA
f. Galaxy Stand	GS
g. Galaxy Quick-Release Bracket	GSQR
h. C-Trak® OmniProbe® Probe Cable	PC
i. Check Source	
Cobalt 57 - 5µCi	CSC5
Cobalt 57 - 10µCi	CSC10
Sodium (Na) 22 - 5µCi	CSS
j. Analyzer and Probe Carrying Case	
Galaxy System	CCCG
Automatic Analyzer System	CCC1
Dual Analyzer System	CCC2
k. C-Trak® OmniProbe® EL device Carrying Case	CCL1
l. C-Trak® OmniProbe® standard device Carrying Case	CCS1

Appendix H (continued)

C-Trak® Systems and Components	Product Code
m. Check Source Holder	
C-Trak® OmniProbe®	CSH
Standard	CSH
C-Trak® OmniProbe® EL devices	CSHL
C-Trak® OmniProbe® PET	CSHP
n. Probe Holster	PH
o. Printer Cable	PRC
p. Remote Repeater Unit, with cable (for Automatic Analyzer System)	RRU
q. Repeater Cable (for Automatic Analyzer System)	RRC
r. Galaxy Cart	GC

5. Service Contracts

ONE Year Maintenance Contract (includes annual preventive maintenance, calibration and certification, return shipping charges, 20% discount on parts and labor, one Check Source, free loaners) on a System will cost 10% of the total current list price of the system to be covered.

All complete systems include: carrying case, check source and check source holder, unless quoted otherwise. Prices are F.O.B. Factory.

All products are covered by a two (2) year warranty, refurbished products are covered by a one (1) year warranty; repaired products are warranted for 90-days.

Contact Care Wise on +1-813-626-6848 (US & Canada) +44 1273 497600 (Europe and Worldwide) or your local Care Wise representative for current pricing information.

Appendix I

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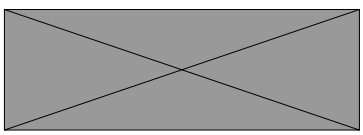
C-Trak Analyzer



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